

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	Of	8	Attorney Docket Number	TUL2BUSA
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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/RAZ/	A	US-6,437,116-B1	08-20-2002	NORRIS et al.	
/RAZ/	B	US-6,475,492-B1	11-02-2002	PHILIPP et al.	
/RAZ/	C	US-2003-0059894-A1	03-27-2003	PHILIPP	
/RAZ/	D	US-5,217,872	06-08-1993	DORWARD et al.	
/RAZ/	E	US-5,403,718	04-04-1995	DORWARD et al.	
/RAZ/	F	US-6,083,722-A	07-04-2000	BERGSTROM et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			
/RAZ/	AA	WO-90/04411	05-03-1990	BERGSTROM et al.	
/RAZ/	AB	WO-91/13630	09-19-1991	SIMPSON et al.	
/RAZ/	AC	WO-91/09870	07-11-1991	FUCHS et al.	
/RAZ/	AD	WO-92/00055	01-09-1992	FLAVELL et al.	
/RAZ/	AE	EP-339,695-A	11-2-1989	BLOEMHOFF et al.	
/RAZ/	AF	EP-465,204-A2	01-08-1992	ACREE et al.	

Examiner Signature		Date Considered	
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U.S. PATENT & TRADEMARK OFFICEINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	8	Attorney Docket Number	TUL2BUSA
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## Complete If Known

Application Number	10/632,780
Filing Date	August 1, 2003
First Named Inventor	Philipp
Group Art Unit	
Examiner Name	

## NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
/RAZ/	AAA	FIKRIG et al., <i>Borrelia burgdorferi P35 and P37 Proteins, Expressed In Vivo, Elicit Protective Immunity, Immunity</i> , May 1997, 6:531-539	
/RAZ/	AAB	ABERER, et al., <i>Molecular Mimicry and Lyme Borreliosis: A Shared Antigenic Determinant Between Borrelia burgdorferi and Human Tissue, December 1989</i> , 26:732-737	
/RAZ/	AAC	GASSMANN et al., <i>N-Terminal Amino Acid Sequence of the Borrelia burgdorferi flagellin, FEMS Microbiol. Lett.</i> , July 1989, 60:101-106	
/RAZ/	AAD	ZHANG et al., <i>Antigenic Variation in Lyme Disease Borrelia by Promiscuous Recombination of VMP-like Sequence Cassettes, Cell</i> , April 1997, 89(2):275-285	
/RAZ/	AAE	RAMAMOORTHY, <i>Molecular Characterization, Genomic Arrangement, and Expression of bmpD, a New Member of the bmp Class of Genes Encoding Membrane Proteins of Borrelia burgdorferi, Infect. Immun.</i> , April 1996, 64(4):1259-1264	
/RAZ/	AAF	ZHANG et al., <i>Kinetics and in vivo Induction of vlsE Antigenic Variation in Borrelia burgdorferi, EMBL/GenBank/DDBJ databases, June 1998, Accession No. AF034515</i>	
/RAZ/	AAG	KAWABATA et al., <i>Genetic and Immunological Analyses of Vls (VMP-like Sequences) in Borrelia burgdorferi, EMBL/GenBank/DDBJ databases, March 1998, Accession No. AB011063</i>	

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Sheet	3	of	8	Attorney Docket Number	TUL2BUSA
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/RAZ/	AAH	ZHANG et al., Kinetics and in vivo Induction of vlsE Antigenic Variation in <i>Borrelia burgdorferi</i> , EMBL/GenBank/DDBJ databases, June 1998, Accession No. AF034525	
/RAZ/	AAI	ZHANG et al., Kinetics and in vivo Induction of vlsE Antigenic Variation in <i>Borrelia burgdorferi</i> , EMBL/GenBank/DDBJ databases, June 1998, Accession No. AF034523	
/RAZ/	AAJ	BARBOUR et al., Variation in a Major Surface Protein of Lyme Disease Spirochete, <i>Infec. Immun.</i> , July 1984, 45:94-100	
/RAZ/	AAK	SIMPSON et al., Reactivity of Human Lyme Borreliosis Sera with a 39-Kilodalton Antigen Specific to <i>Borrelia burgdorferi</i> , <i>J. Clin. Microbiol.</i> , June 1990, 28:1329-1337	
/RAZ/	AAL	HANSEN et al., Immunochemical Characterization of and Isolation of the Gene for a <i>Borrelia burgdorferi</i> Immunodominant 60-Kilodalton Antigen Common to a Wider Range of Bacteria, <i>Infect. Immun.</i> , August 1988, 56:2047-2053	
/RAZ/	AAM	HANSEN et al., Measurement of Antibodies to the <i>Borrelia burgdorferi</i> Flagellum Improves Serodiagnosis in Lyme Disease, <i>J. Clin. Microbiol.</i> , February 1988, 26:338-346	
/RAZ/	AAN	WILSKE et al., Immunochemical and Immunological Analysis of European <i>Borrelia burgdorferi</i> Strains, <i>Zbl. Bakt. Hyg. A.</i> , December 1986, 263:92-102	

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for form 1449B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 8

		Complete if Known	
Application Number		10/632,780	
Filing Date		August 1, 2003	
First Named Inventor		Philipp	
Group Art Unit			
Examiner Name			
Attorney Docket Number		TUL2BUS	A

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/RAZ/	AAO	DORWARD et al., Immune Capture and Detection of <i>Borrelia burgdorferi</i> Antigens in Urine, Blood, or Tissues from Infected Ticks, Mice, Dogs and Humans, <i>J. Clin. Microbiol.</i> , June 1991, 29:1162-1170	
/RAZ/	AAP	BAKKEN et al., Interlaboratory Comparison of Test Results for Detection of Lyme Disease by 516 Participants in the Wisconsin State Laboratory of Hygiene/College of American Pathologist Proficiency Testing Program, <i>J. Clin. Microbiol.</i> , March 1997, 35:537	
/RAZ/	AAQ	DONAHUE et al., Reservoir Competence of White-Footed Mice for Lyme Disease Spirochetes, <i>Am. J. Top. Med. Hyg.</i> , January 1987, 36:92-96	
/RAZ/	AAR	GREEN et al., Immunoblot Analysis of Immunoglobulin G Response to the Lyme Disease Agent ( <i>Borrelia burgdorferi</i> ) in Experimentally and Naturally Exposed Dogs, <i>J. Clin. Micro.</i> , April 1988, 26:648-653	
/RAZ/	AAS	COX et al., Limited Surface Exposure of <i>Borrelia burgdorferi</i> Outer Surface Lipoproteins, <i>Proc. Natl. Acad. Sci. USA</i> , July 1996, 93:7973-7978	
/RAZ/	AAT	KAY et al., In vivo Hepatic Gene Therapy: Complete Albeit Transient Correction of Factor IX Deficiency in Hemophilia B Dogs, <i>Proc. Natl. Acad. Sci. USA</i> , March 1994, 91:2353	
/RAZ/	AAU	ISHIBASHI et al., Hypercholesterolemia in Low Density Lipoprotein Receptor Knockout Mice and its Reversal by Adenovirus-Mediated Gene Delivery, <i>J. Clin. Invest.</i> , August 1993, 92:883	

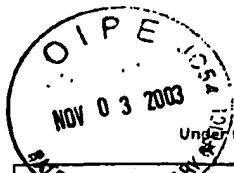
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				Filing Date	August 1, 2003
				First Named Inventor	Philipp
				Group Art Unit	
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Sheet	5	of	8	Attorney Docket Number	TUL2BUSA

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/RAZ/	AAV	ZHANG et al., Kinetics and In Vivo Induction of Genetic Variation of vlsE in <i>Borrelia burgdorferi</i> , <i>Infect. Immun.</i> , August 1998, 66(8):3689-3697	
/RAZ/	AAW	ZHANG, et al., Genetic Variation of the <i>Borrelia burgdorferi</i> Gene vlsE Involves Cassette-Specific, Segmental Gene Conversion, <i>Infect. Immun.</i> , August 1998, 66:3698-3704	
/RAZ/	AAX	KOCHI et al., Facilitation of Complement-Dependent Killing of the Lyme Disease Spirochete, <i>Borrelia burgdorferi</i> , by Specific Immunoglobulin G Fab Antibody Fragments, <i>Infect. Immun.</i> , June 1993, 61:2532-2536	
/RAZ/	AAY	REINITZ et al., Variable and Conserved Structural Elements of Trypanosome Variant Surface Glycoproteins, <i>Mol. Biochem. Parasitol.</i> , February 1992, 51:119-132	
/RAZ/	AAZ	MARRACK et al., Subversion of the Immune System by Pathogens, <i>Cell</i> , January 1994, 76:323-332	
/RAZ/	BBA	GARRITY et al., Refocusing Neutralizing Antibody Response by Targeted Dampening of an Immunodominant Epitope, <i>J. Immunol.</i> , July 1997, 159:279-289	
/RAZ/	BBB	LIGHTFOOT et al., Empiric Parenteral Antibiotic Treatment of Patients with Fibromyalgia and Fatigue and a Positive Serologic Result for Lyme Disease, September 1993, 129:503-509	
/RAZ/	BBC	TUGWELL et al., Laboratory Evaluation in the Diagnosis of Lyme Disease, <i>Ann. Intern. Med.</i> , December 1997, 127:1109-1123	

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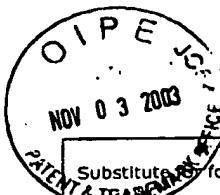
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**INFORMATION DISCLOSURE  
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Sheet 6 of 8

<i>Complete If Known</i>	
<i>Application Number</i>	10/632,780
<i>Filing Date</i>	August 1, 2003
<i>First Named Inventor</i>	Philipp
<i>Group Art Unit</i>	
<i>Examiner Name</i>	
<i>Attorney Docket Number</i>	TUL2BUSA

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/RAZ/	BBD	FOREST et al., Assembly and Antigenicity of the Neisseria gonorrhoeae Pilus Mapped with Antibodies, <i>Infec. Immun.</i> , February 1996, 64:644-652	
/RAZ/	BBE	KAWABATA et al., Genetic and Immunological Analyses of Vls (VMP-like Sequences) of <i>Borrelia burgdorferi</i> , <i>Microb. Pathog.</i> , March 1998, 24:155-166	
/RAZ/	BBF	PHILIPP et al., Safety and Immunogenicity of Recombinant Outer Surface Protein A (OspA) Vaccine Formulations in the Rhesus Monkey, <i>J. Spirochetal and Tick-borne Disease</i> , March 1996, 3:67-79	
/RAZ/	BBG	DESILVA et al., <i>Borrelia burgdorferi</i> OspA is an Arthropod-specific Transmission-blocking Lyme Disease Vaccine, <i>J. Exp. Med.</i> , January 1996, 183:271-276	
/RAZ/	BBH	MATHER et al., <i>Ixodes Saliva: Vector Competence for Borrelia burgdorferi and Potential Vaccine Strategies</i> , in VII International Congress on Lyme Borreliosis, San Francisco, CA, 1996	
/RAZ/	BBI	SADZIENE et al., Antibody-resistant Mutants of <i>Borrelia burgdorferi</i> : In Vitro Selection and Characterization, <i>J. Exp. Med.</i> , September 1992, 176:799-809	
/RAZ/	BBJ	DESILVA et al., Growth and Migration of <i>Borrelia burgdorferi</i> in <i>Ixodes</i> Ticks During Blood Feeding, <i>Am. J. Trop. Med.</i> , October 1995, 53:397-404	

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Application Number	10/632,780
Filing Date	August 1, 2003
First Named Inventor	Philipp
Group Art Unit	
Examiner Name	
Attorney Docket Number	TUL2BUSA

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/RAZ/	BBK	ROSA et al., Recombination between Genes Encoding Major Outer Surface Proteins A and B of <i>Borrelia burgdorferi</i> , <i>Mol. Microbial.</i> , 1992, 6:3031-3040	
/RAZ/	BBL	SCHWAN et al., Distribution and Molecular Analysis of Lyme Disease Spirochetes, <i>Borrelia burgdorferi</i> , Isolated from Ticks throughout California, <i>J. Clin. Microbiol.</i> , December 1993, 31:3096-3108	
/RAZ/	BBM	LIANG et al., Sensitive and Specific Serodiagnosis of Lyme Disease by Enzyme-Linked Immunosorbent Assay with a Peptide Based on an Immunodominant Conserved Region of <i>Borrelia burgdorferi</i> VlsE, <i>J. Clin. Microbiol.</i> , December 1999, 37(12):3990-996	
/RAZ/	BBN	LIANG et al., Analysis of Antibody Response to Invariable Regions of VlsE, the Variable Surface Antigen of <i>Borrelia burgdorferi</i> , <i>Infect. Immun.</i> , December 1999, 67(12):6702-6706	
/RAZ/	BBO	LIANG et al., An Immunodominant Conserved Region Within the Variable Domain of VlsE, the Variable Surface Antigen of <i>Borrelia burgdorferi</i> , <i>J. Immunol.</i> , November 1999, 163(10):5566-5573	
/RAZ/	BBP	ABBAS, et al., Eds., Strategies for Vaccine Development in Cellular and Molecular Immunology, W.B. Saunders Company, Philadelphia, PA: p. 315, 1991	

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PTO/SB/08b (06-03)

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Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<i>Application Number</i>	10/632,780
(Use as many sheets as necessary)				<i>Filing Date</i>	August 1, 2003
				<i>First Named Inventor</i>	Philipp
				<i>Group Art Unit</i>	
				<i>Examiner Name</i>	
Sheet	8	of	8	<i>Attorney Docket Number</i>	TUL2BUSA

**NONPATENT LITERATURE DOCUMENTS**

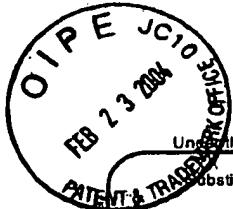
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
/RAZ/	BBQ	BOWIE, et al., Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions, Science, March 1990, vol. 247, pp. 1306-1310	
/RAZ/	BBR	BURGESS et al., Possible Dissociation of the Heparin-binding and Mitogenic Activities of Heparin-binding (Acidic Fibroblast) Growth Factor-1 from Its Receptor-binding Activities by Site-directed Mutagenesis of a Single Lysine Residue, J. Cell Biol, November 1990, vol. 111, pp. 2129-2138	
/RAZ/	BBS	LAZAR et al., Transforming Growth Factor Alpha: Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities, Mol Cell Biol, March 1988, vol. 8 No. 3, pp. 1247-1252	

Examiner Signature	/Robert Zeman/	Date Considered	01/07/2008
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Institute for form 1449/PTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 1 of 1

**Complete if Known**

Application Number	10/632,780
Filing Date	August 1, 2003
First Named Inventor	M. Philipp
Art Unit	1742
Examiner Name	unassigned
Attorney Docket Number	TUL2BUSA

Sheet 1 of 1

**U. S. PATENT DOCUMENTS**

## FOREIGN PATENT DOCUMENTS

**Examiner  
Signature**

/Robert Zeman/

Date Considered

01/03/2008

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## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

Sheet

1

Application Number	10/632,780
Filing Date	August 1, 2003 <i>MAY 24 2004</i>
First Named Inventor	M. Philipp
Art Unit	1645
Examiner Name	R. Zeman

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**U. S. PATENT DOCUMENTS**

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Signature

/Robert Zeman/

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